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April 24, 2013

Susan D. Boresi
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Office of the Missouri Attorney General
P.O. Box 899
Jefferson City, MO 65102

Re: Zink et al. v. Lombardi et al., No. 2:12-CV-4209-NKL

Dear Counsel:

I am writing to address the remaining issues that were left open during yesterday's conference.

First, Dr. Heath is available for a deposition on Saturday, May 18th, beginning at 7:00 a.m. Central Daylight Time. Please let us know if you are available on that date within 24 hours, so that arrangements can be made with minimal disruption to Dr. Heath's schedule and those of the attorneys.

Second, I have attached a proposed joint motion extending the discovery-related deadlines that we discussed. Please advise whether you agree with the attached motion, and if so, I will file it with the court. You will notice that the proposed motion mentions a deadline for discovery-related motions, which is something we did not separately discuss yesterday. If you disagree with the deadline we have proposed, I am confident that the parties can come to an agreement.

Third, Plaintiffs agree to the entry of the protective order that we sent to you on February 22, as to all members of the execution team other than M3. We therefore propose to add the following sentence to the end of paragraph 1 of the protective order:

> Nothing in this order restricts the discovery, disclosure, or investigation of information regarding the witness Defendants have designated as "M3," or any other witness whose professional experience Defendants intend to present in defense of the method of execution announced on May 15, 2012.

We realize that you plan to withdraw your designation of M3 as an "expert" witness. Nevertheless, yesterday's conference made clear that you plan to place M3's medical experience and practice at issue in your defense of the May 2012 protocol—for example, by M3's testimony to medical procedures he has carried out as a practicing anesthesiologist and likening those procedures to some of his tasks under the protocol. Whether or not M3's testimony would fit the definition of "expert opinions," Plaintiffs cannot agree to any restrictions that would prevent

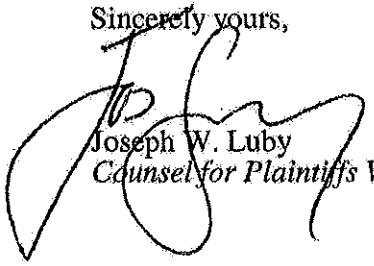
counsel from fully investigating M3 so that counsel can impeach and rebut his testimony as you have described it, and thus refute the inference that the protocol is reasonably pain-free because it benefits from M3's skills and experience. Please let us know if our understanding of M3's proposed testimony is inaccurate.

In this connection, we are confident you appreciate that circumstances have materially changed since Plaintiffs sent the proposed protective order in February. First, the "summary" of M3's opinions, which you served on April 5, suggests that M3 plans to place a femoral line access for each and every execution, that he often places central IV lines in the course of his medical practice, and that he plans to do so during executions in order to prevent pain. Second, you explained yesterday that you intend for M3 to testify as to his professional experience, and thereby to defend the protocol's soundness in light of that experience. Aside from the fact that state law does not apply in this federal lawsuit to enforce federal constitutional rights, we believe that your proposed use of M3's testimony waives any protection or privilege that you might invoke concerning the confidentiality of execution personnel under Mo. Rev. Stat. § 546.720. Finally, you have indicated that the procedures leading up to the administration of the lethal chemicals have not yet been established for the new protocol, and will in fact be established *ad hoc* for each execution. This practice further implicates M3's competence in advising the Department as to preparatory actions needed to keep the execution reasonably pain-free. All of these circumstances make it fundamentally unfair for Defendants to offer M3's testimony as they intend, without also affording Plaintiffs full discovery in order to impeach M3 and rebut his testimony.

If you choose not to rely on M3's experience and practice as a basis for upholding the protocol, we would not insist on disclosure of his identity and qualifications. But under the facts as you have stated them, we believe that the information is necessary for Plaintiffs to have a fair trial and for the Court to consider all relevant evidence.

We realize that the parties may be unable to agree on whether and how to protect M3's identity, and that it may be wise to postpone his May 9 deposition until that issue is resolved. In the meantime, please advise us whether you agree to the proposals we have outlined above.

Sincerely yours,



Joseph W. Luby
Counsel for Plaintiffs Winfield and Cole

IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF MISSOURI
CENTRAL DIVISION

EARL RINGO, et al.,	)	
	)	
Plaintiffs,	)	
	)	
v.	)	Case No. 09-4095-CV-C-NKL
	)	
GEORGE LOMBARDI, et al.,	)	
	)	
Defendants.	)	

Protective Order

In this action, the plaintiffs are Missouri inmates facing execution by lethal injection. The plaintiffs allege that the defendants (collectively referred to as the "Missouri Department of Corrections" or "the Department") violate the federal Controlled Substances Act and the federal Food Drug and Cosmetics Act during the course of execution.

Certain documents, information and tangible objects that may be produced during the course of discovery in this action contain information that may lead to discovery of the identity of persons who serve, or will serve, on the Department's execution team. These documents, information, and tangible objects may

also reveal the names of the companies who supply the Department with the lethal injection chemicals. The Department believes that public disclosure of this information would be contrary to the public safety and the security, privacy, and anonymity interests of the Department and its execution personnel.

The Federal Rules of Civil Procedure empower the Court to enter, for "good cause shown" and when "justice [so] requires," protective orders designed to prevent "a party or person from annoyance, embarrassment, oppression, or undue burden or expense." Fed. R. Civ. P. 26(c). In order to permit Plaintiffs to discover information relevant to this case without undermining the Department's legitimate confidentiality concerns, and pursuant to Rule 26(c) of the Federal Rules of Civil Procedure, the parties stipulate, and it is hereby ORDERED:

1. This Order shall govern any interrogatory responses, documents or other materials produced during discovery as well as all testimony at any deposition or pretrial hearing or proceeding in this action, whether in response to any

discovery request or subpoena made pursuant to the Federal Rules of Civil Procedure or otherwise, and any copies, abstracts, excerpts, analyses, summaries, or other materials (whether in written, electronic, or other form) which contain, reflect or disclose information from such documents, testimony or other materials. The testimony, documents and materials referenced in this paragraph collectively shall constitute "Discovery Materials."

2. Notwithstanding any provisions of this Order to the contrary, the names, addresses, dates and places of birth, professional licensing numbers, and Social Security numbers of any officers, employees, agents and/or contractors involved as execution team members in past executions or expected to be involved in future executions as execution team members shall not be revealed to anyone, including Plaintiffs and counsel for Plaintiffs. "Execution team members" are those individuals who will participate, or are expected to participate in the administration of the lethal injection procedure and who will be given "John Doe" or "John Roe"

designations in this case. As provided in paragraph 12, Plaintiff's reserve the right to seek modification of the paragraph if the disclosed licensing and registration documents are redacted to such an extent that Plaintiffs cannot ascertain the validity of the documents or the scope of activities authorized by them.

3. Counsel for Defendants will provide counsel for Plaintiffs with a John Doe or John Roe designation for each of the aforementioned individuals, as well as a generic identification of each person's credential or title as relates to his or her execution duties, for example "Nurse" or "Emergency Medical Technician," as well as his or her role(s) within the execution team, for instance "Team Leader" or "Syringe Pusher." Should any individuals be added to the DOC's execution team during the course of this litigation, counsel for Defendants shall promptly disclose the existence of each such added individual, assign each new execution team member a John Doe or John Roe designation, and disclose their credential, title, and role within the execution

team. Outside of discovery authorized by the Federal Rules of Civil Procedure, counsel for Plaintiffs may not conduct investigations of those persons counsel for Plaintiffs believe to be involved in past executions, nor of those expected to be involved in future executions. For example, neither counsel, nor anyone acting on their behalf, may contact schools, former employers or credentialing agencies in an effort to determine the identity of, or gain background information on, the aforementioned persons because to do so would pose an unacceptable risk that their participation and identities would be made public. During the course of this litigation, only the John Doe or John Roe designation, or other generic identifier (such as "the Emergency Medical Technician" or "the Team Leader," as suits the convenience and needs of the parties), shall be used to denote any member of the execution team. Nothing in this Order shall be construed to prevent Plaintiffs' counsel from inquiring during a deposition or other discovery process into the education, professional background, board certification, licensing or credentialing of

members of the execution team, except that members' names, identifying numbers on licenses and other credentials, and any other uniquely personal identifiers solely as set out in paragraph 2, shall be governed by the terms of paragraph 2. Nothing in this paragraph shall be construed to expand or otherwise alter the protections set forth in paragraph 2 of this Order.

4. Counsel for either party to this litigation may initially designate as "Confidential" hereunder any Discovery Materials if counsel reasonably believes, in good faith, that the materials implicate Defendants' institutional security interests or privacy concerns; or contain information that could be used to identify any members of the execution team who are, or will be, designated as "John Doe" defendants in this case. Thus, for example, Defendants have the right, before disclosure to Plaintiffs' counsel, to designate as "Confidential" any Discovery Material they produce or provide, if counsel deems, in good faith, that release of such material would compromise any of the security, privacy,

and/or anonymity concerns expressed above, including but not limited to disclosing Defendants' security procedures. Either party designating material as "Confidential" hereunder represents thereby that it has done so in good faith and pursuant to a bona fide belief that such materials are in fact confidential and deserving of protection.

5. In designating material as "Confidential," the party so designating it shall identify the protected material with specificity in writing or on the record during a deposition or other legal proceeding. Either party's counsel may, at any time, object to the designation of material as protected. In the event of any such objection, the designating party's counsel agrees to confer with counsel for the objecting party as promptly as practicable to attempt to resolve the objection informally. Should the designating and objecting parties be unable to resolve the objection informally, the objecting party may submit such dispute to the Court for resolution. Until the Court resolves the dispute, the material shall be

treated as protected and subject to the conditions set forth in this Order.

6. Confidential material provided formally or informally during the course of this litigation shall be handled and disclosed by the parties only as follows:

a. Confidential material may be used only for the purposes of this litigation and shall not be given, shown, made available, discussed, or otherwise communicated in any form to all Plaintiffs nor to anyone other than:

i. counsel for Plaintiffs, including counsel's employees only insofar as is necessary for purposes of this litigation, outside consultants and experts retained by Plaintiffs to assist their counsel for purposes of this litigation, to the extent necessary for such consultants or experts to prepare a written opinion, prepare to testify, or to otherwise assist counsel for Plaintiffs in the prosecution of this action, provided

that such use is solely in connection with this action and not for any other purpose;

ii. any person agreed upon in writing by all counsel in this lawsuit;

iii. court employees, court reporters, and persons preparing transcripts of depositions; and

iv. witnesses in the course of deposition where counsel has a reasonable and good faith belief that examination with respect to the document is necessary for legitimate discovery purposes.

b. It shall be the responsibility of counsel to bring this Order to the attention of all persons within their respective firms and all outside consultants and experts to whom they disclose protected material, and to ensure that all such persons comply with the terms of this Order. Except for counsel of record in this action and those persons described in paragraph 5(a)(iii), any person to whom Confidential material is disclosed shall, prior to receiving such material, be furnished

with a copy of this Protective Order, and a copy of the Notification of Protective Order, in the form attached hereto as Exhibit A, which the person shall read and sign.

c. In the event that any material designated under this Protective Order as Confidential is used, described, characterized, excerpted or referenced in, or attached to, any document filed in this litigation:

i. it shall not lose its confidential status through such use; and

ii. the parties shall agree upon a means of filing that prevents the public disclosure of material designated as Confidential. For instance, the parties may agree to redact Confidential information from public filings, or may agree to file pleadings or Confidential material under seal. The parties shall cooperate in good faith in an effort to ensure that only those portions of filings with the Court

designated as Confidential shall be redacted or filed under seal.

d. All copies made of any material that is subject to this Order shall be clearly labeled on each page as containing "Confidential" material and shall be returned to the party who originally produced them or destroyed at the conclusion of this litigation (including any and all appeals). All materials designated "Confidential" shall be so marked prior to the exchange of those materials between the parties. Where it is not possible to affix a stamp or mark indicating that the material is "Confidential," counsel for Defendants shall take reasonable steps to give counsel for Plaintiffs notice of the materials' status as "Confidential." Legal memoranda and briefs containing protected material and any work product materials containing protected material may be retained if such documents shall be kept in the possession of a private litigant's counsel or in the possession of a governmental entity, and shall

not in the future be disclosed contrary to the provisions of this Order.

e. Deposition testimony may be designated as "Confidential" before the testimony is transcribed by so stating on the record at the deposition or by providing written notice to all counsel, the court reporter, and all attendees at the deposition prior to the taking of the testimony. If deposition testimony is so designated prior to transcription, the transcript of the designated testimony shall be bound in a separate volume from any testimony that has not been so designated and marked "Confidential" by the reporter and shall not be made part of the public record. Regardless of designation made prior to transcription, each deposition transcript in its entirety shall be treated as "Confidential" until ten days after the receipt of the transcript by counsel for Defendants. Until ten days after Defendants' counsel's receipt of the transcript,

Defendants may designate testimony as "Confidential" by giving written notice to Plaintiffs' counsel.

f. Counsel shall endeavor to avoid revealing Confidential material in any oral proceedings before the Court, including oral argument. If any counsel finds it necessary to refer to Confidential material in any such oral proceeding, counsel shall notify the Court and all other counsel of record as soon as such necessity becomes apparent and shall propose whatever mechanism(s) may be available and appropriate to prevent disclosure of Confidential material as a consequence of such oral proceedings to persons other than those authorized by this Order.

6. Counsel shall promptly report any breach of the provisions of this Order to the Court and counsel for the party whose protected material was divulged or compromised. Upon discovery of any breach, counsel shall immediately take appropriate action to cure the violation and retrieve any Confidential material that may have been disclosed to

persons not covered by this Order. Counsel shall also cooperate fully in any investigation of such breach conducted by the Court.

7. By providing any document or other information in its possession, no party waives any privileges, objections, or protection otherwise afforded to it by law or equity.

8. The parties are hereby authorized to seek the admission into evidence at the trial of this case any materials, or the contents thereof, that are designated pursuant to this Order, and nothing contained herein shall be construed as precluding Plaintiffs or Defendants from introducing any such materials, or the contents thereof, into evidence, subject to such measures as the Court may deem appropriate or necessary at that time in order to protect the Defendants' anonymity, privacy, and/or security concerns.

9. Any specific part or parts of the restrictions imposed by this Protective Order may be terminated at any time by a letter from counsel for the designating party or by an order of the Court.

10. This Order is without prejudice to the rights of any party to make any objection to discovery permitted by the Federal Rules of Civil Procedure, or by any statute or other authority, or to the rights of any party to make evidentiary objections at trial.

11. Nothing in this Order may be taken or construed as a ruling or statement concerning the admissibility of any documents or information.

12. This Order is without prejudice to the rights of any party to seek from the Court the modification of this Order.

s/ NANETTE LAUGHREY
Nannette Laughrey,
District Judge

June 24, 2010
Date

IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF MISSOURI
CENTRAL DIVISION

EARL RINGO, et al.,	)	
	)	
Plaintiffs,	)	
	)	
v.	)	Case No. 09-4095-CV-C-NKL
	)	
GEORGE LOMBARDI, et al.,	)	Acknowledgment of and
	)	Consent to Be Bound
Defendants.	)	by Protective Order

The undersigned hereby acknowledges that he (she) has read the Protective Order entered on _____, 2010 in the above-captioned lawsuit, understands its terms, and agrees to be bound by each of those terms. Specifically, and without limitation upon such terms, the undersigned agrees (a) not to use or disclose any Confidential documents or information made available to him (her) other than in accordance with the Protective Order; and (b) to submit to the jurisdiction of the Court in respect of the enforcement of the Protective Order and redress for the violation of the terms thereof.

Dated: _____ ___, 2010

By: _____
Printed Name: _____
Title: _____
Name of Employer:

IN THE UNITED STATES DISTRICT COURT FOR THE WESTERN DISTRICT OF MISSOURI CENTRAL DIVISION

EARL RINGO, et al.,	)	
	)	
Plaintiffs,	)	
	)	
v.	)	Case No. 2:09-cv-04095-NKL
	)	
GEORGE A. LOMBARDI, et al.,	)	
	)	
Defendants.	)	

ORDER

Missouri death row inmates ("Plaintiffs") seek a declaration from the Court that Defendants violate the Controlled Substances Act ("CSA"), 21 U.S.C. §§ 801, *et seq.*, and the Food, Drug and Cosmetic Act ("FDCA"), 21 U.S.C. §§ 301, et seq., when they follow Missouri's protocol for execution by lethal injection. Plaintiffs also seek an injunction preventing Defendants from carrying out executions in a manner that violates these statutes. Before the Court are the parties' cross-motions for summary judgment. For the following reasons, Defendants' Motion for Summary Judgment [Doc. # 213] is GRANTED, and Plaintiffs' Motion for Summary Judgment [Doc. # 209] is DENIED.

I. Factual Background[1]

[1] The Court has considered the parties' statements of undisputed fact which are supported by evidence. In considering each party's motion, the Court has drawn all inferences in favor of the non-movant.

Plaintiffs, other than Richard Clay, are death-sentenced prisoners convicted of first-degree murder under Missouri law. Plaintiff Martin Link has now been executed. Defendant George A. Lombardi is Director of the Missouri Department of Corrections ("DOC") and has ultimate authority for overseeing and supervising Missouri executions, including the authority to change the types and dosages of drugs to be administered under the state's execution protocol.

The DOC's execution team consists of four members, including two medical personnel and two non-medical personnel; these members are anonymously designated M2, M3, NM1, and NM2. Previous medical personnel M1 is a physician who is no longer a member of the execution team. Defendant M2 is licensed as a Missouri Licensed Practical Nurse (LPN), is IV-certified under state law, and performs general nursing duties at a rural hospital, including caring for post-surgical patients. Defendant M2 has been a contracted member of Missouri's execution team for twelve years and has participated in approximately 57 executions in this state. Defendant M2 believes that he is not qualified, by virtue of his nursing licensure or otherwise, to administer the three drugs outlined in Defendants' execution protocol, including the Schedule III controlled substance sodium thiopental.

Defendant M3 is a board-certified anesthesiologist who is licensed to practice medicine in the state of Missouri, and he practices in a private group of anesthesia providers who serve a particular hospital. Defendant M3 has a controlled substances registration through the Missouri Bureau of Narcotics and Dangerous Drugs. M3 states that he has a similar registration through the federal Drug Enforcement Agency. M3 is under contract

with the Department of Corrections to assist with Missouri executions, and, in that capacity, he participated in the execution of Dennis J. Skillicorn on May 20, 2009. Defendants NM1 and NM2 are the non-medical personnel of the execution team, both of whom are employed by the Department of Corrections in non-medical capacities, and neither of whom has any verified medical training.

Plaintiffs claim that Defendants violate the CSA and FDCA by failing to obtain valid medical prescriptions for drugs that are administered to prisoners according to Missouri's execution protocol and by having non-medical personnel dispense controlled substances–the lethal injection drugs–through an "IV push." Plaintiffs term these failings as the "non-prescription problem" and the "IV-push problem."

A. The Execution Protocol

Defendants' execution protocol entails the administration of three drugs into the prisoner: sodium thiopental, pancuronium bromide, and potassium chloride. Sodium thiopental is administered in order to make the prisoner unconscious. The dosage of five grams of sodium thiopental, as called for in the execution protocol, may cause death. [Plaintiffs' Ex. 5 (M3 Depo.), at 57, 72-73]. Pancuronium bromide is a muscle relaxant and paralytic; it is administered in order to stop the prisoner's breathing, and also to prevent involuntary muscular twitching and seizure activity so that the prisoner may have a more peaceful and dignified death. [Doc. # 247, at 3 (citing Defendants' explanation in previous litigation for the use of pancuronium bromide)]. Potassium chloride is administered in order to stop the prisoner's heart.

The lethal injection drugs are prepared by the medical personnel. Anesthesiologist M3 dissolves a total of 5 grams of sodium thiopental powder in water, then draws this solution into four separate syringes, each containing a total of 50 cc of solution. M3 prepares four additional syringes containing an additional 5 grams of thiopental, in case additional thiopental is needed to render the prisoner unconscious or otherwise to complete the execution. Nurse M2 prepares a syringe containing 60 milliliters of solution with 60 milligrams of pancuronium bromide; because this drug arrives already in solution, M2 simply draws the solution into the syringe. In the same manner, M2 draws two syringes, each containing a 60 cc solution with 120 milliequivalents of potassium chloride.

Medical personnel are responsible for attaching IV lines into the prisoner, and this task is usually performed by the physician. M2 attaches the EKG leads to the prisoner, whose condition and level of consciousness are monitored by the medical personnel. Non-medical personnel, NM1 and NM2, directly administer the lethal injection drugs by attaching a syringe to a "port" along the IV line that flows into the prisoner, and then pushing the contents of the syringe into the IV line. NM1 and NM2 inject four syringes containing a total of 5 grams of thiopental, after which medical personnel assess whether the prisoner is unconscious. If the prisoner is not yet unconscious, then NM1 and NM2 would administer additional thiopental. NM1 and NM2 administer 30 cc of saline solution after the thiopental. If medical personnel conclude that the prisoner is unconscious, and so long as at least three minutes have elapsed since the beginning of the administration of thiopental, then NM1 and NM2 administer the syringe of pancuronium bromide, then a second syringe of saline

solution, then two syringes of potassium chloride, and finally a third syringe of saline solution. M3 pronounces the prisoner's death after all electrical activity of the heart has ended. After the execution, all members of the team–specifically, M2, M3, NM1, and NM2–complete required paperwork confirming that the three drugs were injected into the prisoner in the amounts specified by the protocol. These forms are reviewed, approved, and signed by DOC Director Lombardi, and Division of Adult Institutions Director Tom Clements.

If a prisoner were to be administered pancuronium bromide in the amount called for in Defendants' protocol, but without first being anesthetized, the prisoner would experience a painful suffocation while conscious. [Plaintiffs' Ex. 5 (M3 Depo.), at 58 ("Q: So the Sodium Thiopental anesthetizes them from these discomforts and this pain? A: Correct.")]. If a prisoner were to be administered potassium chloride in the amount called for in Defendants' protocol, but without first being anesthetized, the prisoner would experience a painful burning sensation, and would also likely experience chest pain associated with coronary arrest.

Defendants administer thiopental to the prisoner in order to make him unconscious so that he does not experience pain and physical suffering from the other two lethal injection drugs. Defendant M3 stated that such use of sodium thiopental has a medical purpose. [Plaintiffs' Ex. 5 (M3 Depo.), at 54-55]. Anesthesiologist M3 participates in executions in order to, among other reasons, ensure that the prisoner does not suffer pain. M3 considers himself the condemned prisoner's doctor. [Plaintiffs' Ex. 5 (M3 Depo.), at 112-13].

According to Nurse M2, his role during an execution is to "help comfort the patient," in accordance with his professional nursing duties. As part of his role, M2 offers the condemned prisoner comfort and reassurance: "I'm the nurse, and I'm here to help you try to get through this." He offers the prisoner an oral sedative, places a pillow behind his head, asks whether the prisoner needs a drink of water or another pillow, explains that the EKG leads will feel cold but do not hurt, and warns that the IV insertion will cause a mild "stick" or pinching sensation. By offering reassurance, helping to manage the prisoner's anxiety, dispensing oral sedatives, and placing EKG patches, M2 performs services that are comparable to those he otherwise performs as an LPN nurse. M2 believes that a nurse is required in order to perform these services, and "the person who benefits from my services is my patient." [Plaintiffs' Ex. 3 (M2 Depo.), at 172-73].

Defendants' Answer refers to the condemned prisoner as a "patient." [Doc. # 178, ¶ 124 ("Defendants admit in the sense that a non-medical member of the execution team actually pushes the plunger that pushes the chemical into the tubing, although the chemicals are prepared by a board certified anesthesiologist who is present and monitoring the patient during the execution.")].

Medical personnel M2 and M3 evaluate the prisoner's medical history by reviewing a pre-execution questionnaire. The medical questionnaire alerts the medical personnel to aspects of the prisoner's medical history that might complicate an execution, such as damaged veins due to chronic abuse of intravenous drugs. One purpose of assessing the prisoner's medical history is to address conditions that may lead to pain or discomfort during

the execution; among other potential problems, a chronic drug abuser may be "tolerant" of sedatives like thiopental.

Approximately four and one-half hours before the execution, Nurse M2 offers the condemned prisoner an oral sedative, specifically, Valium (also known as Diazepam), for therapeutic or medical purposes. The purpose of the oral sedative is to help the prisoner relax, and to reduce his level of anxiety. Although most executed prisoners have declined the offer of a sedative, M2 may offer the prisoner up to two 5 milligram doses of Valium. In the event that a prisoner suffers an unusually severe degree of anxiety, M3 may administer intravenous or injected sedatives, including Versed (also known as Midazolam), Ketamine, Haldol, and Flumazenil (also known as Romazicon). M2 cannot intravenously administer these sedatives because such a "controlled substance IV push" is beyond the scope of his LPN licensure and medical training.

B. Lack of Prescriptions

Sodium thiopental is a Schedule III controlled substance. Pancuronium bromide and potassium chloride are federally regulated drugs that are available only by prescription. No medical prescriptions–either a traditional prescription or a doctor's oral prescription later reduced to writing–have ever been issued for any of the lethal injection drugs involved in Missouri executions, and Defendants do not currently use or employ such prescriptions when carrying out executions. Defendants do not intend to require or incorporate the issuance of medical prescriptions into Missouri's execution process even though federal law requires a prescription from a doctor for these drugs.

C. Administration of Intravenous Drugs

Non-medical personnel, NM1 and NM2, inject the sodium thiopental, pancuronium bromide, and potassium chloride into the inmate by pushing the contents of seven different syringes into a "port" connected to the prisoner's IV line, approximately 30 inches away from where the IV enters the prisoner. NM1's and NM2's administration of the lethal injection chemicals amounts to an "IV push," which occurs when medicine is drawn into a syringe and is then administered directly into a port along the IV line. Medical personnel observe NM1 and NM2 as they inject the three lethal injection chemicals into the prisoner's IV line. NM1 and NM2 have no verified medical credentials or licenses, and they are employed by the Department of Corrections in non-medical positions. NM1 and NM2 are not federally registered to dispense controlled substances, including sodium thiopental. NM1 and NM2 were not taught how to perform their drug-injecting responsibilities by a physician; rather, DOC personnel train all medical and non-medical members of the execution team, and M3 observes NM1 and NM2 when they empty the syringes during practice executions.

The four syringes containing thiopental, which are administered by NM1 and NM2, each contain a total of 50 cc of solution; the two syringes of potassium chloride and the one syringe of pancuronium bromide each contain 60 cc of solution. NM1 and NM2 are supposed to inject the syringes containing the lethal injection drugs at a rate of approximately 1 cc per second. If the IV push were to be performed too rapidly during an execution, it could cause the prisoner's vein to rupture, which, in the case of thiopental, could prevent the drug from reaching its intended destination in order to anesthesize the prisoner. In addition,

sodium thiopental causes a painful burning sensation when injected into muscle tissue as opposed to a vein.

In the course of Anesthesiologist M3's medical practice, non-medical persons never carry out IV pushes. In the course of his nursing practice, M2 never performs IV pushes of medication. M2's nursing licensure does not allow him to conduct an IV push unless he is in an emergency situation and is being directly supervised by a physician. M2 does not ever administer intravenous sedating drugs, including thiopental, in the course of his nursing practice, because to do so is beyond the realm of his expertise and professional licensing. When treating patients, M2 is not professionally qualified to carry out a "controlled substance IV push" because he does not have any license or certification to dispense or administer controlled substances. Specifically, M2 is not professionally qualified or authorized to administer to any medical patient any of the three lethal injection drugs involved in Missouri executions. In M2's opinion, if the task of administering the three lethal injection chemicals were transferred to him, he would have to withdraw from the execution team, due to the limitations of his nursing license.

The execution team conducts rehearsals or practices of executions on a roughly quarterly basis, and it uses actual execution drugs in the process. The purposes of the simulated executions include giving NM1 and NM2 the opportunity to practice the proper rate of pushing the lethal injection chemicals, and M3 watches NM1 and NM2 practice this task. At the time of the filing of the motions, Defendants had a stock of 50 grams of thiopental, or enough to carry out five executions. This stock expired on March 1, 2011.

Because of the DOC's dwindling supply of thiopental, the execution team's training session of October 12, 2010, did not involve the practiced mixing or administration of actual thiopental.

D. No FDA Approval

The Federal Drug Administration has not approved, either singly or in combination, the use of sodium thiopental, pancuronium bromide, or potassium chloride for the execution of prisoners, including for the medical purpose of preventing or suppressing pain. The FDA has expressed the position that it does not regulate or approve chemicals for use in executions by lethal injections. Defendants have not sought the FDA's approval to use these or any other drugs during executions. Anesthesiologist M3, in the course of his medical practice, does not write a prescription for an anesthesia drug because it is administered by himself or another anesthesia specialist. M3 does not specifically know whether the FDA has approved sodium thiopental, pancuronium bromide, or potassium chloride for executions, but he does not issue medical prescriptions for these or any other drugs in the course of an execution.

Hospira, Inc., is the sole domestic manufacturer of sodium thiopental. Hospira has publicly stated that its pharmaceuticals should not be used for lethal injection. Defendants' supply of sodium thiopental has been manufactured by Hospira, which also manufactures some or all of the pancuronium bromide and potassium chloride that Defendants have obtained for the purpose of carrying out executions. Defendants are aware of Hospira's statements that its drugs, including sodium thiopental, should not be used during executions.

Defendants do not inform their supplier of the purpose for which they intend to use sodium thiopental, pancuronium bromide, and potassium chloride.

E. Valium

Diazepam, or Valium, is a Schedule IV controlled substance. M2, a licensed practical nurse (LPN), is the first medical member of the team to arrive at an execution, and he offers the prisoner an oral Valium tablet. No prescription or standing doctor's order is issued for Valium/Diazepam. M2 does not have a license or other professional certificate allowing him to dispense or administer controlled substances. Valium is a federally regulated drug that is available only by prescription.

F. Risk of Harm

Plaintiffs have obtained an affidavit from board-certified anesthesiologist Mark J.S. Heath, M.D., who is on the medical faculty at Columbia University in New York City, and who has described the relevant medical risks from the "IV-push problem" and "non-prescription problem" in detail. [Plaintiffs' Opposition Ex. D]. According to Dr. Heath, Missouri's execution procedures, as described in the protocol and Defendants' depositions, create "an unacceptable likelihood that a prisoner will have some level of consciousness during his execution," and thereby give rise to "substantial and medically unacceptable risks of inflicting excruciating pain and suffering on inmates while the lethal injection is administered." [*Id.* at 2-3].

According to Dr. Heath, the fact that Defendants delegate to non-medical personnel the task of administering the sodium thiopental through an IV push "represents a gratuitous

source of risk that the execution will be botched and agonizing" and creates a "gratuitous and substantial risk that anesthetic depth will be inadequate and that the execution will be agonizing." [*Id.* at 5-6]. Dr. Heath opines that a lay person lacks the experience and qualifications needed to gauge and act upon the varying degree of "back-pressure" sensed by an anesthesia specialist while injecting a syringe. That skill is necessary in order to determine when an anesthetic such as thiopental is being pushed into the patient's circulatory system through the vein, as opposed to infiltrating the surrounding tissue. Dr. Heath states that proper administration requires a grasp of medical subtlety that is simply unavailable to non-medical personnel. According to Dr. Heath, it is not clinically acceptable for Defendants to rely on a pre-arranged injection rate of 1 cc per second, as NM1 and NM2 are instructed and trained, because there is no "one size fits all" rate of injection of drugs. "Instead, the correct rate of injection depends on factors such as the size of the IV catheter and the geometry of its situation in the vein and the attributes of the veins that are receiving the drug, and since these factors vary tremendously it is necessary to tailor the injection rate." [*Id.* at 5]. According to Dr. Heath, Defendants' failure to customize the rate of injection represents a "gratuitous and substantial departure from acceptable practice and is a direct result of the delegation of the injection process to lay individuals." [*Id.*].

Dr. Heath also opines, to a reasonable degree of medical certainty, that anesthesiologist M3's inability to exercise his independent medical judgment, such as by prescribing the choice of anesthetic and its manner of administration, presents "a gratuitous and substantial risk of a cruel execution." [*Id.* at 6].

II. Discussion

Article III of the United States Constitution grants federal courts limited jurisdiction to decide "cases and controversies." To satisfy this jurisdictional requirement, a plaintiff must establish (1) an injury in fact which is (2) fairly traceable to the defendant's conduct and which (3) will likely be redressed by a favorable decision. *See Friends of the Earth, Inc. v. Laidlaw Envtl. Servs. (TOC), Inc.*, 528 U.S. 167, 180-181 (2000). The party invoking federal jurisdiction must "show that he personally has suffered some actual or threatened injury as a result of the putatively illegal conduct of the defendant," and that the injury "fairly can be traced to the challenged action" and "is likely to be redressed by a favorable decision." *Valley Forge Christian College v. Americans United for Separation of Church and State, Inc.*, 454 U.S. 464, 472 (1982) (quotations omitted).

At this stage of litigation, injury in fact requires a "factual showing of perceptible harm." *Committee to Save the Rio Hondo v. Lucero*, 102 F.3d 445, 449 (10th Cir. 1996). Here, Plaintiffs state that due to what they term the "IV-push problem" and the "non-prescription problem" caused by Defendants' alleged violations of the CSA and FDCA, they are at risk of vein rupture and ineffective sedation, which can result in severe pain or cruel execution. Plaintiffs argue that they "need not show that they will certainly, or even probably, suffer pain as a result" of Defendants' alleged violations. [Doc. # 247, at 18]. They assert that it is "well-settled that a risk of injury or suffering may create a cognizable injury in fact." [Doc. # 226, at 11 (emphasis omitted)]. However, for the reasons explained

below, the Court finds that Plaintiffs are incorrect in their assertion that the risk they describe is sufficient to demonstrate a cognizable injury in fact.

Plaintiffs suggest that medical licensing laws and common medical practice corroborate their assertion that the degree of the risk of harm to Plaintiffs, which is caused by Defendants' violations, is unreasonable. Additionally, Plaintiffs point to the statements of Dr. Mark Heath that Missouri's protocol of delegating the IV-push to non-medical personnel gives rise to "substantial and medically unacceptable risks of inflicting excruciating pain and suffering on inmates while the lethal injection is administered." [Plaintiffs' Opposition Ex. D at 2-3]. He similarly opines that Anesthesiologist M3's inability to exercise his independent medical judgment, which stems from the non-prescription problem, presents "a gratuitous and substantial risk of a cruel execution." [*Id.* at 6]. Plaintiffs, however, do not indicate that such harm has ever occurred to any of the Plaintiffs, or to any individual who had been subject to Missouri's protocol or to any other person executed elsewhere under similar circumstances.

Plaintiffs state that such "threatened injuries" present an injury in fact. However, even an unreasonable risk of harm remains just that--a risk or a possibility of future harm. Recognizing mere risk of injury as injury in fact is counter to well established jurisprudence that an injury in fact must be a "concrete and particularized injury that is either actual and imminent," *Massachusetts v. E.P.A.*, 549 U.S. 497, 518 (2007) (citing *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560-61 (1992)), and not a "mere possibility in the remote future." *Pierce v. Soc'y of the Sisters of the Holy Names of Jesus & Mary*, 268 U.S. 510, 536 (1925).

Here, Plaintiffs point to no evidence that the harm has ever occurred. As it stands, Plaintiffs fail to show any perceptible, present harm. The case law presented to the Court by Plaintiffs in support of their argument that mere risk of harm is sufficient to demonstrate injury in fact does not convince the Court otherwise.

Plaintiffs rely on *Dimarzo v. Cahill*, 575 F.2d 15 (1st Cir. 1978), as the "clearest illustration" of Plaintiffs' standing. [Doc. # 247, at 18]. The plaintiffs in that case were prisoners who charged the Commissioner of Correction and other officials under Section 1983 for numerous unconstitutional conditions and practices. According to the district court, one of the more serious allegations was the condition of the jail as a fire hazard. *Id.* at 16. The Court of Appeals specifically noted evidence submitted to the district court concerning the hazardous fire conditions of the jail: evidence of a serious fire at the jail in February 1975; affidavit testimony that inmates set small fires in their cells; and the personal inspection of the jail by the district judge and his conclusion that it presented a serious fire hazard. *Id.* at 18 n.4. Indeed, there were few exits from the cells, the floors were made of wood and covered in several layers of old paint or flammable covering, the cells could only be unlocked individually, and mattresses were made of material that was flammable or emitted toxic gas when ignited. *Id.* at 16.

The defendants in *Dimarzo* argued that the plaintiffs lacked standing because they failed to demonstrate an injury in fact. According to defendants, plaintiffs needed to show that they would "inevitably . . . suffer physical injury or death from fire" before acquiring standing to challenge the hazardous fire conditions at the jail. *Id.* at 18. The court rejected

this argument: "We find this proposition to fall far below contemporary expectations of constitutionally-mandated humane treatment. One need not wait for the conflagration before concluding that a real and present threat exists." *Id.* at 18. Thus, the injury in fact suffered by the plaintiffs in *Dimarzo* was not the mere risk of future physical harm or death by fire. Rather, the injury in fact was the plaintiffs' ongoing imprisonment in hazardous, inhumane conditions. Such a reading of *Dimarzo* comports with established jurisprudence. Causes of action under the Eighth Amendment for conditions-of-confinement claims can be to remedy potential, serious, future harms, but inmates must demonstrate that it is the current, ongoing prison conditions that pose a substantial risk for those harms. *See Farmer v. Brennan*, 511 U.S. 825, 823 (1994); *Helling v. McKinney*, 509 U.S. 25, 35 (1993); *see also Jacob v. Clarke*, 129 Fed. Appx. 326, 330 (8th Cir. 2005).

Thus, Plaintiffs' reliance on *Dimarzo* is misplaced because the case does not support their contention that hypothetical risk of injury is a cognizable injury in fact. Rather, the jail was found to be hazardous because a fire had taken place in the jail in February 1975 and there was a pattern of small fires set by inmates in their cells while surrounded by highly flammable material; the evidence also suggested that if a fire occurred the prison was maintained in a way that would make it difficult to rescue prisoners. Here, Plaintiffs assert that the selection and administration of sodium thiopental by non-medical personnel creates a risk of injury, but, unlike in *Dimarzo* they have not shown that such harm previously occurred. Further, there is a doctor who is present during the process and the participants rehearse the process. While the actual participants have not been able recently to use the

drugs during rehearsals, there is no evidence that the absence of drugs in the IV solution, alters the process. It remains a hypothetical risk without the likely if not inevitable consequences that were present in *Dimarzo.*

Similarly unavailing is Plaintiffs' dependence on *Massachusetts v. E.P.A.*, 549 U.S. 497 (2007), and *Missouri Coalition for Environment v. Federal Energy Regulatory Commission*, 544 F.3d 955 (8th Cir. 2008). In *Massachusetts v. E.P.A.*, the Supreme Court considered whether Massachusetts had standing to sue the EPA for its decision to decline regulating the emission of various greenhouse gases. The Court found that the "serious and well recognized" harms associated with climate change comprised the injury suffered by Massachusetts. *Id.* at 521. Many of these harms have already been inflicted, such as the "earlier spring melting of ice on rivers and lakes, and the accelerated rate of rise of sea levels during the 20th century relative to the past few thousand years." *Id.* at 521 (citation omitted). Specifically, the rise in sea levels had already "begun to swallow Massachusetts' coastal land." *Id.* at 522. Thus, while the Court recognized that Massachusetts' interests included Massachusetts' coastal property, whether owned by the State, it specifically found that "[b]ecause the Commonwealth owns a substantial portion of the state's coastal property, it has alleged a particularized injury in its capacity as a landowner." *Id.* at 522.

Massachusetts v. E.P.A. is distinguishable from this case on two grounds. First, Massachusetts' injury included harm already suffered–the loss of coastal land due to rising sea levels–not merely projected future harms. Second, any injury that would occur in the future was "serious," "well recognized," and certain to come based on a "strong consensus"

in the relevant scientific community. *Id.* at 521. Here, Plaintiffs present neither an injury already suffered nor demonstrate any certainty that Plaintiffs will ever be subject to severe pain due to the "IV-push problem" or the "non-prescription problem." Thus, Plaintiffs present merely an abstract injury that fails to meet the threshold showing for an injury in fact.

In *Missouri Coalition for Environment v. Federal Energy Regulatory Commission*, 544 F.3d 955 (8th Cir. 2008), the plaintiffs alleged that the defendant, a federal agency, failed to obtain an environmental impact statement prior to authorizing the construction of a hydroelectric generating plant. Key to the court's injury in fact analysis was that the environmental harm at issue stemmed from defendant's non-compliance with the procedural requirements of the National Environmental Policy Act. *Id.* at 957 ("Injury under NEPA occurs when an agency fails to comply with the statute. The injury-in-fact is increased risk of environmental harm stemming from the agency's allegedly uninformed decision-making."). Thus, the increased risk of environmental harm alone was not the injury in fact; rather, the injury in fact was the coupling of the agency's non-compliance under the National Environmental Policy Act and the increased risk of environmental harm which was the very harm intended to be avoided. The Court of Appeals clearly stated that the context of its injury in fact finding was "injury under NEPA." *Id.*; *see also Comm. to Save the Rio Hondo v. Lucero*, 102 F.3d 445, 448-49 (10th Cir. 1996) ("The injury of an increased risk of harm

due to an agency's uninformed decision is precisely the type of injury the National Environmental Policy Act was designed to prevent.").[2]

Plaintiffs call the risk "unreasonable" because the method of administering sedation to Plaintiffs does not conform with medical licensing laws or common medical practice. While the Court acknowledges that medical licensing laws are intended to ensure proper care of patients and to minimize potential harm, Plaintiffs have not shown that the failure to comply with such rules under these particular circumstances necessitates the conclusion that there exists a substantial risk of harm.

Finally, even if the Plaintiffs have sufficiently established a concrete, particularized injury, the Court on further reflection, is not convinced that Plaintiff's preemption claim is viable. However, it need not reach that question because it finds as a preliminary matter that Plaintiffs have not established injury in fact.

III. Conclusion

Accordingly, it is hereby ORDERED that Defendants' Motion for Summary Judgment [Doc. # 213] is GRANTED. Plaintiffs' motion [Doc. # 209] is DENIED.

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[2]While it appears that Missouri is violating federal law by failing to obtain its execution drugs with a doctor's prescription and by failing to use a doctor to administer the drugs, the Court does not believe that *Missouri Coalition for Environment v. Federal Energy Regulatory Commission* means that injury in fact is established when a state is violating federal law and there is some theoretical risk of injury as a result. To so find would require the Court to resolve the merits of the case before deciding whether there was an injury and would mean that any violation of federal law would establish injury in fact, if the Plaintiff might be harmed by it.

s/ NANETTE K. LAUGHREY
NANETTE K. LAUGHREY
United States District Judge

Dated: August 15, 2011
Jefferson City, Missouri